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K 123617

MAY 1 5 2013

Section 5 **510(k) SUMMARY** **Traditional 510K**

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x2271 Fax: (215) 256-9191
Contact:	Jessica Leo Regulatory Associate
Date Prepared:	November 16, 2012

B. Trade Name: Medcomp® 3F PRO-PICC® CT

Common Name:	Catheter, Intravascular, Therapeutic, Long-Term
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970
Class:	II

C. Predicate Devices:

K091953 Medcomp, PRO-PICC® CT, class II 880.5970
K091586 Medcomp, Vascu-Picc & Midline, class II 880.5970
K102159 Bard Access Systems, Inc., PowerPICC SV Catheter, class II 880.5970

D. Device Description:

The 3F PRO-PICC® CT catheter is an open-ended lumen catheter designed for power injection and pressure monitoring. The 3F PRO-PICC® CT catheter is comprised of a soft radiopaque polyurethane material. The lumen has a reverse taper design and is connected to the extension via a soft pliable hub with suture wing for secure placement. The clamp on the extension tube prevents air/fluid communication. The female luer connector provides the connection for intravenous administration. The power injectable extension line is purple in color to differentiate it from non-power injectable catheters. The extension is also is printed with the words power injectable. The I.D. Ring within the clamp contains information regarding checking for blood return and flushing along with rate of infusion for power injection.

The 3F PRO-PICC® CT catheter is available with a single lumen. The catheter has a usable length of 50cm with depth markings in 5 cm increments. Stylet and adaptor sideport are provided to assist in catheter insertion.

The catheter is packaged sterile in a variety of tray configurations with the necessary accessories to facilitate catheter insertion.

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E. Indications for Use:

The 3F PRO-PICC® CT catheter is indicated for short term or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media, and allows for central venous pressure monitoring. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

F. Comparison to Predicate Devices:

The 3F PRO-PICC® CT catheter is substantially equivalent to the predicate devices in terms of intended use, anatomical location, basic design, materials, performance, labeling, manufacturing process and method of sterilization.

The differences between the 3F PRO-PICC® CT and the predicate devices is a smaller French size with a CT injectable and a shorter taper of 2 to 5 cm versus 7 to 10 cm.

G. Bench / Performance Data:

Performance testing of the proposed device was conducted in accordance with applicable international standards and FDA guidance documents. Performance standards for pressure injection have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act. Testing is based upon internal engineering testing methods.

The results of these tests in conjunction with the substantial equivalence claims effectively demonstrate the proposed devices are equivalent to the predicate devices.

H. Biocompatibility:

Testing for all materials used for the 3F PRO-PICC® CT has been submitted in previously cleared Medcomp devices. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993.

I. Technological Characteristics:

Technological similarities between the proposed device and predicate devices remain the same.

J. Summary of Substantial Equivalence:

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Ms. Jessica Leo
Regulatory Associate
Medical Components Incorporated
1499 Delp Drive
HARLEYSVILLE, Pennsylvania 19438

Re: K123617
Trade/Device Name: 3F PRO-PICC® CT
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 24, 2013
Received: May 3, 2013

Dear Ms. Leo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Ruth Purohitsheth

Tejashri S. Purohitsheth -S
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123617

Device Name: 3F PRO-PICC ® CT

Indications for Use:

The 3F PRO-PICC® CT catheter is indicated for short term or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media, and allows for central venous pressure monitoring. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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